510(k) Summary for the MEDICREA® INTERNATIONAL PASS LP Spinal System

FEB 0 5 2013

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the PASS LP Spinal System.

Date Prepared: September 9, 2012

1. **Submitter:**

MEDICREA INTERNATIONAL
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Contact Person:

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2. **Trade name:** PASS LP Spinal System

   Common Name: Spinal fixation appliances

   Classification Name: Pedicle screw spinal system
   §888.3070

   Classification and Regulation:
   OSH Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis
   MNH Orthosis, Spondylolisthesis Spinal Fixation
   MNI Orthosis, Spinal Pedicle Fixation
   KWP Appliance, Fixation, Spinal Interlaminal

3. **Predicate or legally marketed devices which are substantially equivalent:**

   - The PASS LP Spinal System (MEDICREA, K110497)
   - The TSRH Spinal System (MEDTRONIC, K111942)

4. **Description of the device:**

The PASS LP Spinal System is designed to contribute to correction and surgical stabilization of the thoracic, lumbar and sacral spine.

The system consists of pedicle screws, hooks, sacral plates, iliac screws, clamps, rods, nuts, rod plates and crosslink components. It can be used for single or multiple level fixations. Components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 or cobalt-chromium-molybdenum alloy Co-Cr28Mo6 that conforms to ISO 5832-12 and ASTM F1537.

A subset of PASS LP Spinal System components may be used for posterior pedicle screw fixation in pediatrics cases. These constructs may be comprised of a variety of shapes and sizes of rods, hooks, sacral plates, iliac screws, clamps, nuts and crosslink components. Similarly to the PASS LP implants used in adult case, these components can be rigidly locked into a variety of configurations, with each construct being tailored-made for the individual case.

Materials: Titanium alloy and Cobalt-chromium-molybdenum alloy

Function: The PASS LP was developed as an implant:

- To provide immobilization and stabilization of posterior spinal segments
- to augment the development of a solid spinal fusion
- to provide stability to ease fusion
- to be mechanically resistant to allow the fusion of the operated level

5. Intended Use

The PASS LP Spinal System includes a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

- Fractures
- Dislocation
- Failed previous fusion (Pseudoarthrosis)
- Spinal stenosis
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Spinal deformations such as scoliosis or kyphosis.
- Loss of stability due to tumors.

The PASS LP Spinal System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The PASS LP also includes hooks and rods and sacral/iliac screws indicated for degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS LP Spinal System is intended to be used with allograft and/or autograft. Pediatric pedicle screw fixation is limited to a posterior approach.

6. Substantial equivalence claimed to predicate devices

MEDICREA® INTERNATIONAL PASS LP Spinal System is substantially equivalent to the MEDTRONIC TSRH Spine System, in terms of intended use, materials used, mechanical safety and performances.

- The TSRH Spinal System (MEDTRONIC, K111942)

The table below compares the features and characteristics of MEDICREA® INTERNATIONAL PASS LP Spinal System to this predicate device.

Device	TSRH (MEDTRONIC)	PASS LP Spinal System
510(k) number	K111942	In progress
Intended use		
	The TSRH Spinal System is intended for use as a pedicle screw fixation system of the non cervical posterior spine in skeletally mature patients using allograft and/or autograft. The TSRH Spinal System is indicated as an adjunct to fusion for one or more of the following: degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies); degenerative spondylolysthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and/or failed previous fusion (pseudarthrosis).	MEDICREA® INTERNATIONAL PASS LP Spinal System includes a pedicle system intended to provide immobilization and stabilization of spina segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine: fracture, dislocation, failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis ans loss of stability due to tumors
Design		
Fundamental scientific technology	Posterior rod and screw system with medial rods.	Posterior rod and screw system with medial rods.
Connection of components	The pedicle screw is connected to the rod using a connector which provides an offset that allows positioning the rods medial to the pedicle	The pedicle screw is connected to the rod using a connector which provides an offset that allows positioning the rods medial to the pedicle
Range	- Rods and pre-bent rods, - Pedicle screws, - Nuts, - Connectors, - Cross connectors, - Hooks, - Dominos, - Sacral connection, - Iliac connection	- Rods and pre-bent rods, - Pedicle screws, - Nuts, - Connectors, - Cross connectors, - Hooks, - Dominos, - Sacral connection, - Iliac connection
Materials		

Device	TSRH (MEDTRONIC)	PASS LP Spinal System
All components	Titanium alloy conforming to ASTM F136	Titanium alloy conforming to ASTM F136
Rods	Cobalt-28-Chromium-6Molybdenum Alloy conforming to ASTM F1537	Cobalt-28-Chromium-6Molybdenum Alloy conforming to ASTM F1537

Material composition is identical to other MEDICREA® INTERNATIONAL products that have been cleared via the 510(k) process.

7. Non-clinical Test Summary:

The PASS LP Spinal System submitted by MEDICREA in this 510k includes only components that have been approved by the FDA in the previous 510Ks (K062136, K080099, K082069, K082577, K083308, K083810, K100297, K110497, K112493) for the following indications:

The PASS LP Spinal System includes a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: fracture, dislocation, failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis and loss of stability due to tumors.

The PASS LP Spinal System is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The PASS LP also includes hooks, rods and sacral/iliac screws indicated for degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

The purpose of this new submission is to extend the indications for use to adolescent idiopathic scoliosis. No other changes in terms of design characteristics, principles of operation, packaging, sterility, biocompatibility or mechanical performances have undergone.

Mechanical testing of the MEDICREA® INTERNATIONAL PASS LP implants was conducted following the ASTM F1717 *"Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model"* to characterize the mechanical properties of the device. MEDICREA® INTERNATIONAL PASS LP additional components cleared in special 510(k) was also tested following the ASTM F1798 *"Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanism and Subassemblies Used In Spinal Arthrodesis Implants"* to characterize their mechanical properties.

These data was compared to the mechanical performance for other devices cleared for surgical fixation of the skeletal system.

Accordingly, the mechanical performance of INTERNATIONAL PASS LP Spinal System implants has been established via these cleared devices **(K062136, K080099, K082069, K082577, K083308, K083810, K100297, and K110497)**

8. Clinical Test Summary

No clinical studies were performed

9. Conclusions Nonclinical and Clinical

MEDICREA PASS LP Spinal System is substantially equivalent to its predicate devices in terms of indications for use, design, material and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

Medicrea International
% Ms. Audrey Vion
Regulatory Affairs Manager
14 Porte du Grand Lyon
01700 Neyron - France

Re: K123138
Trade/Device Name: PASS LP Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: OSH, MNI, MNH, KWP
Dated: September 20, 2012
Received: November 8, 2012

Dear Ms. Vion:

This letter corrects our substantially equivalent letter of February 5, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K123138

Device Name: PASS LP Spinal System

Indications for Use:

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Prescription Use ✓	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123138